



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** Submit your comments to [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov) or by calling (202) 795-7714.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990-0473-60D and project title for reference, to Sherrette A. Funn, email: [Sherrette.Funn@hhs.gov](mailto:Sherrette.Funn@hhs.gov), [PRA@HHS.gov](mailto:PRA@HHS.gov), or call (202) 795-7714 the Reports Clearance Officer.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: HHS Subpart C Certification Form

Type of Collection: Revision

OMB No. 0990-0473

Abstract: The Office for Human Research Protections (OHRP) is requesting a three-year approval on a revision of OMB No. 0990-0473, the HHS Subpart C Certification Form. The purpose of this form is to provide a simplified, standardized procedure for institutions to submit subpart C research certifications to OHRP in order to obtain authorization to include prisoners in HHS-conducted or supported human subjects research. The form also simplifies the internal process used by OHRP to review and record such certifications, resulting in faster processing while reducing unnecessary and burdensome staff time.

Likely Respondents: Institutions or Organizations operating Institutional Review Boards (IRBs) that have enrolled or are planning to enroll prisoners in human subjects research conducted or supported by HHS.

Annualized Burden Hour Table

Form name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden hours
Subpart C Certification Form	25	2	1.0	50
Subpart C Certification Form	5	3	1.0	15
Total				65

**Sherrette A. Funn,**

*Paperwork Reduction Act Reports Clearance Officer,*

*Office of the Secretary.*

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